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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/226,597	01/07/99	PIMENTEL J	585-017-84

022850 HM22/0217
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EXAMINER	
GABEL, G	
ART UNIT	**PAPER NUMBER**
1641	4

DATE MAILED: 02/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/226,597	Pimentel
Examiner	**Group Art Unit**
Gailene R. Gabel	1641

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-9 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting " an effective amount" because the term "effective" is a relative term that lacks a comparative basis for defining its metes and bounds.

Claim 2 is indefinite for depending upon itself.

Claim 9 has improper antecedent basis problem in reciting "a liposome-encapsulated immunoglobulin." Change to --the liposome-encapsulated immunoglobulin-- for proper antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,919,451) in view of Laurent et al (EP 0310931) and Leclercq et al. (Reproduction, Nutrition, and Development, 1990, Abstract only).

Cook et al. disclose a method for regulating the body weight (improving the growth) of an animal or improving efficiency of the animal to convert its feed into desirable body tissue, i.e. lean. Cook et al. specifically disclose feeding an animal a food composition comprising an optionally liposome-encapsulated immunoglobulin or antibody (particles with non-fat nutrients in inner core surrounded by antibody) that help protect the animal from disease or other antigens, i.e. lipase, that can affect the animal's growth or efficiency (see column 1, line 62 to column 2, line 6). Alternatively, the antibodies can be provided as wet or freeze dried liposome-encapsulated antibodies (in solution/suspension or in an aqueous lipid carrier or directly applied to the pellet core without a carrier such as a powder (dried). The avian antibodies are obtained from the egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (see column 2, lines 22-29). Cook et al. specifically disclose passively immunizing animals by orally administering to said animals effective amounts of egg-derived materials containing avian antibodies which are obtained by immunizing egg-laying hens with specific antigens, i.e. lipase, which will produce such antibodies, then obtaining the antibody containing egg material from eggs laid by the hen (column 1, lines 41-52). Such antibodies can alter physiological processes that adversely affect growth and feed efficiency or they can be

antibodies that are against diseases or against specific endogenous regulators of food intake or gastrointestinal mobility, i.e. lipase (see column 3, lines 5-14). Finally, Cook et al. disclose applicability of his method to preparing animal feed for pets and other animals (see column 6).

Cook et al. fail to disclose specifically choosing lipase as the antigen to which the liposome encapsulated immunogloblin binds. Cook et al. fail to teach a specific amount of antibody contained into the food composition of claim 6, specifically 25-1000mg/kg.

Laurent et al. teach a method of providing a poultry feed containing an effective amount of an antilipogenic agent for lowering lipid levels in poultry, Such method provides a means of increasing lean/fat ratio in poultry (see page 2).

Leclercq et al. teach anti-lipoprotein lipase antibodies for use in studying very low density lipoproteins (VLDL) and compared its effect on metabolism between fat and lean lines of chicken. Since lipoprotein lipase is known to catalyze hydrolysis of plasma lipoproteins, the action of antilipase antibodies is investigated in its capacity to affect metabolism by inhibiting adipose activity and reducing fat accumulation in chickens (see Abstract).

One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in incorporating lipase as the antigen which the antibodies bind as taught by Leclercq and suggested by Laurent, in the method of Cook et al. because Cook et al. specifically disclose using antibodies for regulating body weight in poultry and that one can specifically select endogenous regulators of metabolism as the antigen such as lipase, and Leclercq et al. teach the role of lipase in catalyzing hydrolysis of plasma and Laurent et al.

specifically disclose that antilipase (or antilipogenic agent) lowers lipid levels in poultry (see column 3, lines 5-14). One of ordinary skill in the art would have been motivated to incorporate both teachings of Laurent et al. and Leclercq et al. into the method of Cook et al. because Cook et al. disclose applicability of their method to a wide variety of uses in altering physiological processes that adversely affect growth, health, and feed efficiency animals in order to acquire healthier, disease-free animals, especially those raised for consumption.

Cook et al. is silent on teaching a specific amount of antibody contained into the food composition of claim 6, specifically 25-1000mg/kg. However, Cook et al. specifically disclose administering **a safe and effective amount** of an antibody that would help protect the animal from disease or other antigens that can adversely affect an animal's growth or the efficiency of the animal to convert feed into desirable body tissue. It is, therefore, maintained that the amount of antibody contained in a food composition should be a safe and effective quantity. Such range in value therefore renders an amount that is representative of a result effective variable which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value

of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitation recited in instant claim 9 is for any particular purpose or solve any stated problem and the prior art teaches that quantities may vary according to level of effectiveness in a particular animal, acceptable effective parameters appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies used in the method disclosed by the prior art by normal optimization procedures known in the poultry feeding art.

3. For reasons aforementioned, no claims are allowed.

Remarks

4. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Uster et al. (US 5,064,655) disclose liposome gel composition and method.

Ivey et al. (US 5,976,580) disclose nutrient formulation and process for enhancing the health, livability , cumulative weight gain or feed efficiency in poultry and other animals.

Ivey et al. (US 5,985,336) disclose nutrient formulation and process for feeding young poultry and other animals.

Bentley et al. (US 4,863,959) disclose derivatives as useful agents for promoting growth, improving feed efficiency, and for increasing the lean meat to fat ratio of warm blooded animals.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

2-14-00

Gail Gabel
Patent Examiner
Group 1641

James C. Housel 2/14/00

JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER